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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,361	08/25/2003	Mark L. Weiss	13807.1USI1	2222

7590 07/10/2006

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EXAMINER	
TON, THAIAN N	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	
Office Action Summary	10/647,361	WEISS ET AL.	
	Examiner	**Art Unit**	
	Thaian N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-46 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-46 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 12, 13, 16-23, 34, 35, 41-43, drawn to methods for obtaining stem cells from an umbilical cord matrix and cultured isolates comprising stem cells isolated from an umbilical cord matrix source of stem cells, methods of generating a bank of stem cells from an umbilical cord matrix, classified in class 435, subclasses 325, 373, 383, for example.

II. Claim 5, drawn to methods of differentiating stem cells to a transplantable cells to produce an ectodermal cell, classified in class 435, subclass 377, for example.

III. Claim 6, drawn to methods of differentiating stem cells to a transplantable cells to produce an endodermal cell, classified in class 435, subclass 377, for example.

IV. Claim 7 drawn to methods of differentiating stem cells to a transplantable cells to produce an neuroectodermal cell, classified in class 435, subclass 377, for example.

V. Claim 8, drawn to methods of treating a mammalian subject for alleviation of a disease symptom using a transformed cell comprising stem cells, classified in class 424, subclass 93.21, for example.

VI. Claims 9-11, 15, drawn to methods of introducing a foreign gene into a stem cell, classified in class 435, subclass 455, for example.

VII. Claims 24-28, 36-40, drawn to methods of transplanting a neural transplantable cell into a patient, classified in class 424, subclass 93.1; class 435, subclasses 325, 368, for example.

VIII. Claims 29-31, drawn to methods of inducing the production of myofibroblast cells and introducing said cells into a patient, classified in class 424, subclass 93.1; class 435, subclasses 325, 371, for example

IX. Claims 44-46, drawn to methods of generating transgenic or chimeric animals, comprising injection of UCMS cells into morulae and/or blastocysts, classified in class 800, subclass 24, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and any of Inventions II-IV, VI and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the undifferentiated stem cell of Invention I can be used to establish an undifferentiated stem cell line, by passaging the cells in an undifferentiated state, under specific culture conditions, such as using particular media and feeder cells, to establish the cell line. The stem cells can also be used in an assay to determine particular markers specific for undifferentiated umbilical cord matrix stem cells to further characterize the cells.

Inventions I and any of Inventions V, VII or VIII are distinct inventions. The stem cells of Invention I are directed to an undifferentiated umbilical cord matrix stem cell. The method of Invention V is directed to using a transformed umbilical matrix stem cell for methods of therapy. The methods of Inventions VI-VIII are directed to using differentiated cells for methods of therapy. The stem cell of Invention I can be used in methods other than those envisioned in Inventions V-VIII, such as in the production of transgenic animals, or in *in vitro* differentiation assays. Each of the inventions requires a separate search because each of the inventions has different technical considerations, which would constitute an undue search burden.

Invention II and any of Inventions III-IX are mutually exclusive and independent. The method of producing an ectodermal cell of Inveniton II is not required for the implementation of the methods of differentiating stem cells to a

transplantable cells to produce an endodermal cell of Invention III, the methods of differentiating stem cells to a transplantable cells to produce an neuroectodermal cell of Invention IV, the methods of treating a mammalian subject for alleviation of a disease symptom using a transformed cell comprising stem cells of Invention V, the methods of introducing a foreign gene into a stem cell of Invention VI, the methods of transplanting a neural transplantable cell of Invention VII, the methods of inducing the production of myofibroblast cells and introducing said cells into a patient of Invention VIII, or the methods of generating transgenic or chimeric animals of Invention IX, and vice versa. Each of the methods requires a materially separate protocol, which requires different technical considerations, with regard to different method steps, reagents, as well as starting materials and end results. Thus, given that each of the methods are independent of each other, a search of Inventions II-IX together would constitute an undue search burden.

Invention III and any of Inventions IV-IX are mutually exclusive and independent. The methods of differentiating stem cells to a transplantable cells to produce an endodermal cell of Invention III are not required for the implementation of the methods of differentiating stem cells to a transplantable cells to produce an neuroectodermal cell of Invention IV, the methods of treating a mammalian subject for alleviation of a disease symptom using a transformed cell comprising stem cells of Invention V, the methods of introducing a foreign gene into a stem cell of Invention VI, the methods of transplanting a neural transplantable cell of Invention VII, the methods of inducing the production of myofibroblast cells and introducing said cells into a patient of Invention VIII, or the methods of generating transgenic or chimeric animals of Invention IX, and vice versa. Each of the methods requires a materially separate protocol, which requires different technical considerations, with regard to different method steps, reagents, as well as starting materials and end results. Thus, given that each of the methods are independent of each other, a search of Inventions III-IX together would constitute an undue search burden.

Invention IV and any of Inventions V-IX are mutually exclusive and independent. The methods of differentiating stem cells to a transplantable cells to produce an neuroectodermal cell of Invention IV are not required for the methods of treating a mammalian subject for alleviation of a disease symptom using a transformed cell comprising stem cells of Invention V, the methods of introducing a foreign gene into a stem cell of Invention VI, the methods of transplanting a neural transplantable cell of Invention VII, the methods of inducing the production of myofibroblast cells and introducing said cells into a patient of Invention VIII, or the methods of generating transgenic or chimeric animals of Invention IX, and vice versa. Each of the methods requires a materially separate protocol, which requires different technical considerations, with regard to different method steps, reagents, as well as starting materials and end results. Thus, given that each of the methods are independent of each other, a search of Inventions IV-IX together would constitute an undue search burden.

Invention V and any of Inventions VI-IX are mutually exclusive and independent. The methods of treating a mammalian subject for alleviation of a disease symptom using a transformed cell comprising stem cells of Invention V are not required for the implementation of the methods of introducing a foreign gene into a stem cell of Invention VI, the methods of transplanting a neural transplantable cell of Invention VII, the methods of inducing the production of myofibroblast cells and introducing said cells into a patient of Invention VIII, or the methods of generating transgenic or chimeric animals of Invention IX, and vice versa. Each of the methods requires a materially separate protocol, which requires different technical considerations, with regard to different method steps, reagents, as well as starting materials and end results. Thus, given that each of the methods are independent of each other, a search of Inventions V-IX together would constitute an undue search burden.

Invention VI and any of Inventions VII-IX are mutually exclusive and independent. The methods of introducing a foreign gene into a stem cell of Invention VI are not required for the implementation of the methods of transplanting a neural transplantable cell of Invention VII, the methods of inducing the production of myofibroblast cells and introducing said cells into a patient of Invention VIII, or the methods of generating transgenic or chimeric animals of Invention IX, and vice versa. Each of the methods requires a materially separate protocol, which requires different technical considerations, with regard to different method steps, reagents, as well as starting materials and end results. Thus, given that each of the methods are independent of each other, a search of Inventions VI-IX together would constitute an undue search burden.

Invention VII and either of Inventions VIII or IX are mutually exclusive and independent. The methods of transplanting a neural transplantable cell of Invention VII are not required for the implementation of the methods of inducing the production of myofibroblast cells and introducing said cells into a patient of Invention VIII, or the methods of generating transgenic or chimeric animals of Invention IX, and vice versa. Each of the methods requires a materially separate protocol, which requires different technical considerations, with regard to different method steps, reagents, as well as starting materials and end results. Thus, given that each of the methods are independent of each other, a search of Inventions VII-IX together would constitute an undue search burden.

Inventions VIII and IX are mutually exclusive and independnent. The methods of inducing the production of myofibroblast cells and introducing said cells into a patient of Invention VIII are not required for the implementation of methods of generating transgenic or chimeric animals of Invention IX, and vice versa. Each of the methods requires a materially separate protocol, which requires different technical considerations, with regard to different method steps, reagents, as well as starting materials and end results. Thus, given that each of the methods are

independent of each other, a search of Inventions VIII-IX together would constitute an undue search burden.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Because each invention has acquired a separate status in the art as a separate subject for inventive effort and require independent searches. The search for each of the above inventions is not co-extensive, particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group, would not necessarily anticipate or even make obvious another group. Accordingly, such a search would be considered undue.

Claim 4 links Inventions II-IV. Claim 23 links Inventions VII and VIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 4 and 23.

Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is

subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Thursday

from 7:00 to 5:00 (Eastern Standard Time). Should the Examiner be unavailable, inquiries should be directed to Ram Shukla, SPE of Art Unit 1632, at (571) 272-0735. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the Official Fax at (571) 273-8300. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

thaian ton

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